From: Charles Boyd <CharlesB@Safechain.com>
Sent: Fri 2/5/2021 4:37:00 PM (UTC)
To: "Martha M. Rumore" <mrumore@frierlevitt.com>
Cc: Abbie Divilio <AbbieD@Safechain.com>
Subject: RE: Biktarvy issue with a customer

Sorry I'm a little confused. How are we as just a wholesaler able to determine if a product is unfit or could cause harm? Isn't that for a doctor to decide? Also, how is this any different than the other issues we've had outside of when the customer notified Gilead? If we contact the FDA on this situation but did not previously on the other issues, I would think that would be a problem. I don't want to open a potential can of worms with the FDA when we really cannot determine if the product is unfit or could cause harm. We have no clue what a product can and cannot do. We just fill orders as requested by the pharmacy.

Maybe it makes more sense to hop on a quick call to discuss?

Charlie Boyd | Founder & CEO
Safe Chain Solutions, LLC
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From: Martha M. Rumore <mrumore@frierlevitt.com>
Sent: Friday, February 5, 2021 11:21 AM
To: Charles Boyd <CharlesB@Safechain.com>
Cc: Abbie Divilio <AbbieD@Safechain.com>
Subject: RE: Biktarvy issue with a customer

Hi

You are required to notify FDA if you make a determination that that product is unfit or likely to cause harm.

Martha M. Rumore, PharmD, MS, JD, LLM
Senior Counsel

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GOVERNMENT EXHIBIT
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1:24-cr-20255-WPD

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From: Charles Boyd <CharlesB@Safechain.com>
Sent: Friday, February 5, 2021 11:17 AM
To: Martha M. Rumore <mrumore@frierlevitt.com>; Abbie Divilio <AbbieD@Safechain.com>
Subject: RE: Biktarvy issue with a customer

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Thanks Martha. What I'm asking is, what are we required by law to do?

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From: Martha M. Rumore <mrumore@frierlevitt.com>
Sent: Friday, February 5, 2021 11:00 AM
To: Charles Boyd <CharlesB@Safechain.com>; Abbie Divilio <AbbieD@Safechain.com>
Subject: RE: Biktarvy issue with a customer

Hi Charlie:

Once the manufacturer is notified, they have the duty to notify FDA also (see the Guidance). The reason it was Gilead's responsibility (and not yours) is that for those past issues your investigation to make a determination consisted of the pharmacy sending product to Gilead and you asking Gilead to look into the matter and provide you with their "determination." However, instead they then turned it around that it was your responsibility to notify FDA and that the transaction with your supplier was illegitimate. I want to avoid this from happening again. The companies are using DSCSA to avoid costly recalls of their product when mixups occur.

Under the circumstances Abbie has described, take the lead to circumvent Gilead from blaming you. You should notify FDA when you receive the written confirmation from the pharmacist. At that point you are able to make a "determination."

Best,

Martha

Martha M. Rumore, PharmD, MS, JD, LLM
Senior Counsel

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From: Charles Boyd <CharlesB@Safechain.com>
Sent: Friday, February 5, 2021 10:42 AM
To: Abbie Divilio <AbbieD@Safechain.com>
Cc: Martha M. Rumore <mrumore@frierlevitt.com>
Subject: Re: Biktarvy issue with a customer

[EXTERNAL SENDER: This message came from an EXTERNAL address. DO NOT click on links or attachments unless you know the sender and the content is safe.]
Hi Martha,

Quick question, we have 24 hours to notify the FDA or Gilead does? Previously you mentioned this was the manufacturers responsibility so I just want to make sure we understand what is required of us. Thanks!

Charlie Boyd | Founder & CEO
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On Feb 5, 2021, at 10:30 AM, Abbie Divilio <AbbieD@safechain.com> wrote:

Good morning Martha,
I have left a voicemail for the pharmacist this morning, and I will try to call him again to get a written statement from him. I will ask that he return the bottle to us. We do not have any other of this lot, and only dispensed the one bottle. Once, I have the pharmacists statement I will send on to you. When the product arrives back to our facility, we will quarantine.

Thanks,

<image001.png>
Abbie Divilio | Director of Compliance
Safe Chain Solutions, LLC
822 Chesapeake Drive | Cambridge, MD 21613
office: 855.437.5727 x1017 | fax: 866.930.1128
www.SafeChain.com |
<image002.png>

From: Martha M. Rumore <mrumore@frierlevitt.com>
Sent: Friday, February 5, 2021 10:26 AM
To: Abbie Divilio <AbbieD@Safechain.com>
Cc: Charles Boyd <CharlesB@Safechain.com>
Subject: RE: Biktarvy issue with a customer

Hi Abbie and Charlie:

Just wanted to follow up from my email yesterday:

The steps are as follows:

1) Quarantine product lot
2) Conduct investigation regarding the suspect product (falls into category D- unfit for distribution such that the product would result in adverse health consequences)
- Your investigation right now involves finding out from pharmacy that they dispensed an unopened bottle and what the bottle was found to contain
- You can ask for the product back or can ask that they send to the manufacturer (either way is OK)
- It is better if you get the product back and then send to Gilead with a cover letter. Otherwise Gilead will attempt to blame you like they did before. To me this sounds like a manufacturing issue at the Gilead plant.
3) Once your investigation is complete and you have made a determination, then you have 24 hours to notify FDA and immediate trading partners regarding the issue reported to you with this lot. I would like to be in a position to say an unopened bottle was dispensed and another Gilead product was found in the bottle.

See the FDA Guidance for your review (p.3, p.6)
https://www.fda.gov/media/88790/download.

Best,
Martha

Martha M. Rumore, PharmD, MS, JD, LLM
Senior Counsel

<image003.png>

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From: Abbie Divilio <AbbieD@Safechain.com>
Sent: Thursday, February 4, 2021 1:39 PM
To: Martha M. Rumore <mrumore@frierlevitt.com>
Cc: Charles Boyd <CharlesB@Safechain.com>
Subject: Biktarvy issue with a customer

[EXTERNAL SENDER: This message came from an EXTERNAL address. DO NOT click on links or attachments unless you know the sender and the content is safe.]
Good afternoon Martha,
Yesterday afternoon we received a call from one of our customers with another claim that the Biktarvy bottle he bought from us, and dispensed to a patient was filled with the wrong medication. The Product was Biktary, NDC 61958-2501-01, Lot CCZCFA. I spoke with the pharmacist today to get a better idea of what happened. He dispensed the whole, unopened bottle to the patient, the patient took the bottle and filled her med box with it. She noticed the color of the pill was different but assumed that the manufacturer changed it. She consumed 16 out of the 30 tabs. She may have been having some adverse effects of the medication, something triggered her to make an appointment with her Dr. Upon inspection of the medication, they came to determine that the Biktarvy was not Biktarvy and was actually another HIV medication (also manufacturer by Gilead) Stribild. The patient returned the remaining medication to the pharmacy. The pharmacist has 9 pills remaining, she had 5 left in her med box, that she will be returning today. The Dr of the patient, did not tell the pharmacist if they filed a report to the FDA or other local agencies. The pharmacy is located in Maryland. We only receive one of this lot, so we have not dispensed it to any other customers. We have not contacted Gilead.

We have some questions:
What should the pharmacy do with the remaining pills? Return to us?
Who should we report this to? Just our supplier who we bought this from?
What is the next step to be sure we are complying with reporting regulations?

Thank you,

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